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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,008	08/07/2006	Toshiharu Suzuki	3749-0112PUS1	7226

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
10/05/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,008	SUZUKI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 10-20* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☒ Claim(s) *20* is/are allowed.

6)☒ Claim(s) *6,10-13 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 12-14 and 19 have been amended and claim 20 added as requested in the amendment filed on August 04, 2009. Following the amendment, claims 6 and 10-20 are pending in the instant application.

2. Claims 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 17, 2008.

3. Claims 6, 10-13 and 16-20 are under examination in the instant office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on August 04, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below. New grounds of objection and rejection necessitated by amendment are set forth below as well.

Claim Objections

6. Claim 12 is objected to for recitation "further which further", which appears to be a typo. Correction or clarification is required.

Claim Rejections - 35 USC § 112, new grounds of rejections

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12-13 and 17-19, **as amended**, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 12 does not make sense. Specifically, the claim is directed to a method which requires determination of a ratio of a high-molecular weight peptide consisting of a fragment of SEQ ID NO: 1 having higher MW than the peptide consisting essentially of any of SEQ ID NOS: 4 to 12 or 14 to 17 wherein an elevated ratio or an increase in ratio is indicative of AD. First, it is not obvious as what embodiment is represented by "a high-molecular weight peptide consisting of a fragment of SEQ ID NO: 1". Considering that peptides of SEQ ID NOS: 4 to 12 or 14 to 17 are fragments of the polypeptide of SEQ ID NO: 1 and also because "consisting essentially of" is interpreted as "comprising" (see reasons of record in section 19 below), one skilled in the art would not know what peptides are included or excluded from the denominator of the ratio to be calculated. Further, the difference in "elevated ratio" and "increased in the ratio" is not clear. Clarification is required.

10. Claim 13 recites limitation "a high-molecular weight peptide which is a fragment of SEQ ID NO: 1" in claim 6. There is insufficient antecedent basis for this limitation in the claim. Provided that the peptides of SEQ ID NOS: 4 to 12 or 14 to 17 are fragments of the polypeptide of SEQ ID NO: 1, it is not clear as what is supposed to be determined.

11. Further, claim 13 recites the limitation "said change in the molecular species of the peptide is a change from the high-molecular-weight peptide to a peptide of any one of SEQ

ID NOS: 4 to 12 or 14 to 17", which is smaller than", which is indecipherable. Applicant is advised to rewrite the claim to better express the claimed subject matter.

12. Similarly, claim 19, as currently amended, does not make sense for reciting interchangeably different fragments of the same polypeptide of SEQ ID NO: 1, which are defined either by reference to the polypeptide of SEQ ID NO: 1, or to SEQ ID NOS: 4 to 12 or 14 to 17 (note that SEQ ID NOS: 4 to 12 or 14 to 17 are all fragments of the polypeptide of the amino acid sequence of SEQ ID NO: 1), or by reference to the MW of the fragment being higher or "smaller".

Applicant is advised that one of the purposes of the 112, second paragraph is to provide a clear warning to others as to what constitutes infringement of the patent (see, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). In precedential decision *Ex parte Kenichi Miyazaki*, Appeal 2007-330, BPAI stated "In particular, rather than requiring that the claims are insolubly ambiguous, we hold that if a claim is amendable to two or more plausible claim constructions, the USPTO is justified in requiring the applicant to more precisely define the metes and bounds of the claimed invention by holding the claim unpatentable under 35 U.S.C. § 112, second paragraph".

Further, the federal Circuit recently stated in *Halliburton Energy Servs.*:

> When a claim limitation is defined in purely functional terms, the task of determining whether that limitation is sufficiently definite is a difficult one that is highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area). We note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and *it is highly desirable that patent examiner demand that applicants do so in appropriate circumstances* so that the

> patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation.

Halliburton Energy Servs. V. M-ILLC 514 F .3d 1244, 1255 (Fed. Cir. 2008) (emphasis added).

13. In the instant case, recitation of a structure of a novel molecular embodiment without a reference to a precise amino acid sequence identified by a proper SEQ ID NO:, does not allow one skilled in the art to appraise the scope of the claimed subject matter, and the metes and bounds of claims remain unclear.

14. Claim 18 stands rejected for reasons of record in section 13 of Paper mailed on May 04, 2009. Applicant argues at p. 6 of the Response that, "claim 18 recites "a first peptide" not "the first peptide". As such, antecedent basis for this feature does not need to be found in claim 10". Applicant's argument has been fully considered but is not persuasive because it does not address the basis of the rejection, which did not cite the lack of antecedent basis for "the peptide", see reasons of record in section 13.

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 12, 13, 17 and 19, **as currently amended**, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

Claims 12, 13, 17 and 19 are directed to methods reciting steps of determination and measurement of various fragments of the polypeptide of SEQ ID NO: 1, ratio(s) between the amounts of these fragments, including assessment of MW of the fragments and comparison thereof. The amendment does not specifically points out to the support for these limitations within the specification as originally filed. The Examiner fails to locate the specific recitation of the subject matter currently claimed, therefore claims 12, 13, 17 and 19 do not satisfy the written description requirement of 112, first paragraph.

17. Claims 10-13 and 16-19 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record in section 16 of Paper mailed on July 07, 2008 and in sections 17-18 of Paper mailed on May 04, 2009. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant traverses the rejection at pp. 7-8 of the Response by citing MPEP 2144.03 and stating that the Examiner has failed to provide any documentary evidence as why the enablement of the instant claimed methods is doubted. Applicant states that "Applicants do not simply assert the enablement of the invention without any evidence. The specification provides examples in a cellular model which are indicative of the enablement of the invention for the diagnosis and prognosis of Alzheimer's disease. These experiments further support the use of the ratio of a higher molecular weight fragment of SEQ ID NO: 1 compared to a peptide of SEQ ID NOS:4-12 or 14-17, which is of lower molecular weight; or a change in such ratio as a diagnostic for

Alzheimer's disease". Applicant's arguments have been fully considered but are not persuasive for the following reasons.

As an initial matter, the basis of the rejection under 35 U.S.C. 112, first paragraph, lack of enablement and full explanation of the enabled subject matter is provided in section 16 of Paper mailed on July 07, 2008. Furthermore, claims 12-13, 17 and 19, as currently presented are rejected for claiming subject matter not originally presented as filed, see reasons of record in section 16 of the instant office action. Thus, Applicant's reasoning that the evidence for the claimed invention is provided within the specification is unavailing.

For reasons of record fully explained earlier, the instant rejection is maintained.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claim 6 stands rejected under 35 U.S.C. 102(b) as being anticipated by Sonderegger et al., 2002, for reasons of record in section 20 of Paper mailed on May 04, 2009.

At p. 9 of the Response, Applicant states that "Applicants agree that under certain circumstances, "consisting essentially of" may be equated with "comprising". However, claim 6 does not fall under such circumstances. It is unequivocally clear from the specification that enlarging the sequences of SEQ ID NOS: 4-12 and 14-17 so as to encompass the full sequence of Sonderegger et al. would render SEQ ID NOS:4-12 and 14-17 unsuitable for their intended use,

i.e. materially affect the invention. As such, "consisting essentially of" cannot be interpreted, for claim 6, as meaning "comprising"". Applicant's argument has been fully considered but it is not persuasive that explanation of utility of the suitable fragments defines structure of the peptides.

Claim 6 is directed to peptides consisting essentially of an amino acid sequence represented by any one of SEQ ID NOS: 4 to 12 or 14 to 17. First, MPEP 2111.01, II makes it clear that "IT IS IMPROPER TO IMPORT CLAIM LIMITATIONS FROM THE SPECIFICATION". Thus, the fact that the specification supposedly describes unsuitable fragments and therefore excludes what is not being claimed, does not have any effect on the instant claimed products.

Further, MPEP 2111.03, Transitional Phrases, states that,

"For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.").

Since in the instant case, the specification does not specifically define or point out the meaning of the limitation "consisting essentially of", the art is applied to the product interpreted as comprising a fragment of SEQ ID NO: 1, which is a full length of the polypeptide fully disclosed in the prior art of Soderegger et al. and the rejection is maintained.

Allowable Subject Matter

20. Claims 10 and 16 if limited to diagnostic method using samples of brain tissue and reciting specific fragments of the polypeptide of SEQ ID NO: 1, are enabled and appear to be free of prior art.

21. Claim 20 is allowed. Suggested language to better express the claimed subject matter is as follows:

Claim 20. An isolated peptide consisting of the amino acid sequence selected from the group consisting of SEQ ID NOS: 4 to 12 and 14 to 17.

Conclusion

22. Claim 20 is allowed. Claims 6, 10-13, 16-19 are rejected.

23. This application contains claims 14-15 drawn to an invention nonelected with traverse in Paper filed on April 17, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

April 28, 2009

/Olga N. Chernyshev/
Primary Examiner, Art Unit 1649